

REMARKS

Currently, claims 2-28, 31 and 46 are pending, and Applicant has added new claims 48-55, which depend from the elected invention (set forth below). No new matter has been added. Applicant has cancelled claims 1, 29-30, 32-45 and 47. Applicant has amended claims 5-28, 31 and 46 in accordance with the elected invention. The Examiner has restricted the claims in the case to fifteen (15) groups broken down as follows:

1. Invention Group I, claims 1 and 5-31, drawn to a method of using one or more double-stranded oligoribonucleotides (dsRNA) to make an undisclosed composition for the specific modulation of the expression of target genes in cells and/or tissues of the CNS and/or eye of a subject; and

2. Invention Group II, claims 2-31 and 46 drawn to a method of using a composition comprising one or more double-stranded oligoribonucleotides (dsRNA) for the specific modulation of the expression of target genes in cells and/or tissues of the CNS and/or eye, wherein said composition is introduced into a cell, tissue or organism outside the blood-brain or blood-retina barrier;

3. Invention Group III, claims 32-39, drawn to a non-human organism comprising a cell or tissue comprising a composition comprising one or more double-stranded oligoribonucleotides (dsRNA).

4. Invention Group IV, claim 40, drawn to a pharmaceutical composition comprising a double-stranded oligoribonucleotides (dsRNA).

5. Invention Group V, claim 41, drawn to a diagnostic composition for detecting a gene or gene expression involved in diseases of the CNS and/or eye.

6. Invention Group VI, claims 42-43, drawn to a method of identification and isolation of a drug capable of specific modulation of the expression of a target gene in cells and/or tissues of the eye.

7. Invention Group VII, claim 44, drawn to a method of using at least one composition of a structurally and functionally diverse genus of compositions for the specific modulation of expression of one or more target genes in cells and/or tissues of the CNS and/or eye.

8. Invention Group VIII, claim 45, drawn to a kit comprising at least one component of a structurally diverse genus of compositions.

9. Invention Group IX, claim 46, drawn to a method of using a cell comprising a composition comprising one or more double-stranded oligoribonucleotides (dsRNA) in drug discovery or target gene isolation and/or validation.

10. Invention Group X, claim 46, drawn to a method of using a non-human organism comprising a cell or tissue comprising a composition comprising one or more double-stranded oligoribonucleotides (dsRNA) in drug discovery or target gene isolation and/or validation.

11. Invention Group XI, claim 47, drawn to a method of using RNA interference for the diagnosis and/or therapy of disorders.

12. Invention Group XII, claim 47, drawn to a method of using a nucleic acid, carrier and/or vector for the diagnosis and/or therapy of disorders.

13. Invention Group XIII, claim 47, drawn to a method of using a non-human organism for the diagnosis and/or therapy of disorders.

14. Invention Group XIV, claim 47, drawn to a method of using a host cell or cell line for the diagnosis and/or therapy of disorders.

15. Invention Group XV, claim 47, drawn to a method of using a tissue or organ for the diagnosis and/or therapy of disorders.

The Examiner has issued further restrictions, as follows:

If any of Invention Groups I-II, V and VII is elected, a further election of a single neural tissue is required. Where the modulation of target genes occurs must be elected, either: (i) in the cells and tissues of the eye; or (ii) in the cells and tissues of the central nervous system.

If any of Groups I-V and VII-XV, a further species election is required as the Examiner has stated that the claims are directed to one or more species of structurally diverse dsRNA molecules: (i) dsRNA molecules between 21 and 23 nucleotides in length; (ii) dsRNA molecules containing a terminal 3'-hydroxyl group; (iii) dsRNA molecules having been chemically synthesized; (iv) dsRNA molecules representing an analogue of naturally occurring RNA; (v) dsRNA analogues differing from the corresponding naturally occurring RNA by addition, deletion, substitution or modification of one or more nucleotides; (vi) dsRNA molecules that inhibit the corresponding target gene by "posttranscriptional silencing"; and (vii) dsRNA molecules encoded by a vector.

If any of Groups I-V and VII-XV, a further species restriction is required as the Examiner has stated that the claims are directed to more than one species of promoter: (i) a cell specific promoter; or (ii) a tissue specific promoter.

If any of Groups I-V and VII-XV, a further species restriction is required as the Examiner has stated that the claims are directed to more than one species of compositions to which the dsRNA is complexed as listed in claims 22 and 23.

If any of Groups I-V and VII-XV, a further species restriction is required as the Examiner has stated that the claims are directed to more than one species of means by which the dsRNA molecule(s) is administered to the eyeball as set forth in claim 26.

If any of Groups I-V and VII-XV, a further species restriction is required as the Examiner has stated that the claim are directed to more than one species of eye diseases. A single eye disease species, wherein the organism displays, must be elected. Specifically, (i) a disease of the inner segment of the eye ball, as recited in claim 36; (ii) a retinal disease, as recited in claim 37; or (iii) a degenerative retinal disease, as recited in claim 38.

Finally, the Examiner has stated that claims 2-4, 27-28, 33-38 and 41-47 are generic as to the organism and a specific organism must be elected.

Applicant elects the invention designated as Invention Group II (Claims 2-31 and 46) directed to a method of using a composition comprising one or more double-stranded oligoribonucleotides (dsRNA) for the specific modulation of the expression of target genes in cells and/or tissues of the CNS and/or eye, wherein said composition is introduced into a cell, tissue or organism outside the blood-brain or blood-retina barrier. In addition, Applicant elects the following species: cells and tissues of the eye as the species of neural tissue; dsRNA molecules between 21 and 23 nucleotides in length as the species of dsRNA molecules; a tissue specific promoter as the species of promoter; a micellar structure as the complex; systemic administration as the species of administration; a degenerative retinal disease as the species of eye disease; and human as the species of organism. By virtue of the election of Invention Group II and the further species elections presented above, Applicant respectfully submits that claims 2-13, 20-22, 24-28, 31, 46, 48-49, and 51-54 are believed to be readable upon the elected species.

Applicant expressly reserves the right to present the claims of Invention Group I and III -XV, or other claims, in one or more divisional, continuation, or continuation-in-part applications at a later date.

CONCLUSION

Applicant has timely filed this response. In the event that an additional fee is required for this response, the Commissioner is hereby authorized to charge such fees to Deposit Account No. 50-0436.

Should the Examiner have any questions or comments, or need any additional information from Applicant's attorney, he is invited to contact the undersigned at his convenience.

Respectfully submitted.

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